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APPENDIX IX

510(k) SUMMARY

**510(k) NUMBER:** PENDING

**SUBMITTED BY:** Applied Medical Resources  
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**DATE OF PREPARATION:** February 27, 1997

**NAME OF DEVICE:** Applied Medical Dual Lumen Embolectomy Catheter

**CLASSIFICATION NAME:** Embolectomy Catheter

**SUMMARY STATEMENT:**

The Applied Medical Dual-Lumen Embolectomy Catheter is a sterile disposable balloon catheter. It is indicated for the removal of arterial thromboemboli, for temporary occlusion, and for infusion of fluids. It may be used with or without a guidewire. The catheter body features two channels through the length of its main body and includes access ports on the inflation and fluid infusion lumens, a Y connector, and a latex balloon on the distal end. Radiopaque marker bands are proximal and distal to the balloon. A 1cc syringe is supplied with the 3F, 4F and 5F models while a 3cc syringe is supplied with the 6F and 7F models.

The Applied Medical Dual-Lumen Embolectomy Catheter is used in the same manner as a conventional embolectomy catheter when only the inflation lumen is utilized. The diseased artery is exposed, clamped, and an arteriotomy is performed. The catheter is inserted into the arteriotomy with or without a guidewire and passed through the clot. The second lumen may then be used for infusion. The balloon is inflated and the clot is extracted.

The Applied Medical Dual-Lumen Embolectomy Catheter is substantially equivalent to the Fogarty® Thru-Lumen Embolectomy Catheter marketed by Baxter Healthcare Corporation. The performance of the balloon is substantially equivalent to the Applied Medical Regular Tip Embolectomy Catheter. Mechanical and biocompatibility tests were performed to verify functional and structural integrity as well as material safety.

All testing demonstrates the Applied Medical Dual-Lumen Embolectomy Catheter to be equivalent to the predicate devices and introduces no new safety and effectiveness issues when used as indicated.